Calendar No. 951

106TH CONGRESS, *2d Session* | SENATE | REPORT 106–504

NATIONAL UNIFORMITY FOR FOOD ACT OF 2000

OCTOBER 17 (legislative day, SEPTEMBER 22), 2000.—Ordered to be printed

Mr. LUGAR, from the Committee on Agriculture, Nutrition, and Forestry, submitted the following

REPORT

[To accompany S. 1155]

The Committee on Agriculture, Nutrition, and Forestry, to which was referred the bill (S. 1155) to amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

CONTENTS

I. PURPOSE, NEED AND BACKGROUND

Statutes authorizing regulations on food, usually on its safety, began in the 19th Century with city ordinances and state statutes. The federal government was authorized to regulate certain foods when Congress enacted the Food and Drugs Act of 1906 and the Federal Meat Inspection Act of 1906. Although national uniformity was discussed at that time, as reflected in the House Report on the Food and Drugs Act of 1906, neither Act gave the federal government sole responsibility for regulating food nor included a provision for national uniformity of food regulation on the state and local level.

In a Senate Report accompanying the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA), Congress recognized the "problem

of uniformity" in the regulation of foods. The report says that "states have unanimously urged the Federal Government to take leadership in modernizing existing law." Since enactment of the 1938 Act, Congress has passed a number of statutory provisions that mandate national uniformity in food regulation and other consumer products. Some of these laws include: identity of food and cosmetic ingredients (1967), net quantity declarations on consumer commodities (1967), meat regulation (1967), poultry regulation (1968), egg regulation (1970), medical device regulation (1976), specified food labeling requirements (1990), pesticide residues in foods (1996), and nonprescription drug requirements (1997).

As part of the Nutrition Labeling and Education Act of 1990, Congress included a national uniformity provision for specified aspects of food labeling, set forth in section 403A of the FFDCA (21 U.S.C. 343–1). This provision succeeded in requiring uniformity in nutrition labeling throughout the United States.

The nation's food regulatory system consists of activities carried out by several federal, state, and local government agencies that inspect, test, research, and monitor the food supply. Under the FFDCA, the Food and Drug Administration (FDA) has the primary responsibility for ensuring that safe food, other than meat, poultry and some egg products, reach American consumers. FDA is also authorized to commission state and local authorities to conduct inspections of food establishments. Because of the immense size of the U.S. food industry, FDA has increasingly used this authority. In June 2000, the Office of the Inspector General of the Department of Health and Human Services (DHHS) issued a report on FDA oversight of state inspections of food establishments. The DHHS Inspector General concluded that "[A]n effective food safety system depends on the collective efforts and coordination among federal, state, and local levels of government."

The United States has a national food supply. Food grown or processed in one part of the country is rapidly transported for marketing throughout the nation. Consumers deserve the same high level of protection against unsafe food regardless of where they may live. National uniformity in food regulation legislation will coordinate and harmonize federal, state, and local food safety requirements and enforcement efforts, and thus will enhance consumer protection throughout the country.

II. SECTION-BY-SECTION ANALYSIS

Section 1. Short title

This section names the bill the National Uniformity for Food Act of 2000.

Section 2. National uniformity for food

This section amends the FFDCA to provide for uniform regulatory requirements for all processed foods except for specific exemptions provided within the legislation. The requirements will allow for uniform regulation throughout the country.

The bill amends the FFDCA in two respects. First, it expands the existing national uniformity requirement for food labeling provisions in section 403A to include food adulteration provisions. Sec-

ond, it adds a new section 403B that specifically requires uniformity in food safety warning notification requirements.

Subsection 2(a). National Uniformity. This subsection amends section 403A to provide the same type of national uniformity for special dietary food labeling and for dietary supplement labeling as now applies under this provision to other types of food. In addition, national uniformity is extended to all aspects of food adulteration other than food sanitation. National uniformity is not applied to food sanitation because states have traditionally provided a leadership role throughout the country in regulating sanitary food practices at the state and local levels.

Subsection 2(b). Uniformity in Food Safety Warning Notification Requirements. This subsection replaces existing section 403B with a new section 403B consisting of eight subsections covering the following subjects: (1) the national uniformity requirement; (2) a procedure under which existing nonuniform state requirements will be reviewed; (3) a procedure for granting exemptions from national uniformity and for adopting state requirements as national standards; (4) authority for states to take immediate action to address an imminent hazard to health; (5) a determination that the legislation has no effect on product liability law; (6) a determination that state and local governments may take whatever action is appropriate to enforce statutory requirements that are identical to the federal requirements; (7) exemptions for traditional local food enforcement activities; and (8) a definition of the term "requirement" that includes both mandatory action and any prohibition under the Federal Food, Drug, and Cosmetic Act or the Fair Packaging and Labeling Act.

Uniformity Requirement. This paragraph establishes a national uniform labeling requirement. The provision requires that any and all forms of label warning requirements are required to be uniform throughout the nation. No state or political subdivision is permitted to require a warning relating to food, including any component or package of the food, unless the specific warning has been required by the FDA and the state warning is identical to the FDA warning. The requirement of national uniformity in food warnings applies to the food label, labeling, advertising, posters, public notices, and any other means of communication. It covers warnings adopted by statute, regulation, or other administrative action. It includes any form of notification requirement for food, whether by a law specifically classified as a food statute, a consumer protection, or unfair competition law, or a law that more generally applies to all chemicals present in consumer products or the environment. The requirement of national uniformity does not apply to any requirement or prohibition that does not involve a notification requirement for the regulated industry.

Definitions. This paragraph provides definitions of the terms "notification requirement" and "warning". Notification requirements are defined as any mandatory disclosure requirement relating to the dissemination of information about a food by a manufacturer or distributor of a food in any manner, such as through a label, labeling, poster, public notice, advertising, or any other means of communication. Warning is defined, as it applies to Section 403B(a)(1), to include any statement, vignette, or other representation that indicates, directly or by implication, that the food pre-

sents or may present a hazard to health or safety. Thus, a requirement that information be disclosed about a food or any of its constituents, based upon public concern about safety, falls within the definition of a warning even though the provision is not specifically designated as a warning. The reason for the notification requirement will determine whether it falls within the definition of a warning.

State and federal authorities often take regulatory action relating to food safety that does not involve a notification requirement. Such activity is subject to the national uniformity provisions of section 403A but is not subject to section 403B of the FFDCA. Though a state may not require a notification requirement that provides for a warning that has not also been required by the FDA, that state remains free to issue its own warning, under state statutory authority, whenever such a warning is justified. Similarly, any mandatory recall order or court injunction involving food adulteration under a state statutory requirement that is identical to a federal food adulteration statutory requirement is also exempt from national uniformity.

Construction. This paragraph provides that nothing in this section is to be construed to prohibit a state from conducting the state's notification, disclosure, or other dissemination of information, or to prohibit any action taken relating to a mandatory recall or court injunction involving food adulteration under a state statutory requirement identical to a food adulteration requirement under this Act.

Existing State Requirements; Deferral. This paragraph provides for review of existing state requirements. Numerous states presently have notification requirements for a food that provide for a warning or a food adulteration requirement that does not meet the uniformity requirement set forth in this legislation. The bill provides that these requirements shall remain in effect for 180 days after the date of enactment. After this time existing requirements are to be reviewed by FDA if a state makes this request and a determination made as to whether they will be exempted from the requirement of national uniformity or be adopted as a national standard that applies throughout the country.

State petitions. This paragraph provides guidelines to allow states to petition FDA to allow a state notification requirement described in Sec 403B(b)(1) to remain in effect or become a national standard. A state must petition FDA within 180 days after the date of enactment of this legislation for this review to occur. A state law that is the subject of such a petition automatically remains in effect until such time as FDA takes full administrative action as provided under this provision.

Action on petitions. Within 270 days after the date of enactment, FDA is required to publish a notice of the petition in the Federal Register and to provide 180 days for public comment. The agency is then required to take final agency action on the petition within 360 days after the time for comment expires. If FDA fails to meet the statutory deadlines it will constitute a final agency action that permits the petitioner to obtain a court order enforcing a reasonable timetable. If FDA were to violate these statutory deadlines, the aggrieved party has a statutory right to judicial review in order

to obtain a court order requiring FDA to comply within a reasonable time period.

These provisions assure that existing state requirements will not arbitrarily be superseded upon enactment of the new law. If a state can justify either an exemption from the requirement of national uniformity, or a national need to adopt the state requirement as a uniform standard applicable throughout the country, that state provision will remain in effect.

Exemptions. This paragraph provides that any state may petition FDA to obtain an exemption from the requirement of national uniformity for a requirement of either the state or a political subdivision of the state. The legislation allows exemptions from national uniformity and the adoption of a state requirement as a uniform national standard. FDA may grant the exemption if the state or local requirement protects an important public interest that would otherwise be unprotected, would not cause the food to be in violation of any federal law, and would not unduly burden interstate commerce.

National Standards. This paragraph provides that states may petition FDA to establish by regulation a national standard. These provisions recognize that special circumstances may justify a warning requirement in a particular state or locality even though that requirement should not apply throughout the country. Thus, the need for local protection is fully recognized under the legislation. In addition, if the need is national, the legislation provides that any state may petition FDA to establish by regulation a national standard that will apply to the entire country.

Action on petitions. The legislation provides specific procedures to assure that FDA will give adequate attention to either an exemption petition or a national standard petition. Within thirty days after the receipt of either type of petition, FDA is required to publish the petition in the Federal Register for public comment. FDA must then either take action on the petition or explain why it cannot act within 60 days after the end of the time for public comment. Under no circumstances may FDA take longer than 120 days for action. If FDA were to violate these statutory deadlines, the aggrieved party has a statutory right to judicial review in order to obtain a court order requiring FDA to comply within a reasonable time period.

Judicial review. If FDA fails to meet the statutory deadlines it will constitute a final agency action that permits the petitioner to obtain a court order enforcing a reasonable timetable. If FDA were to violate these statutory deadlines, the aggrieved party has a statutory right to judicial review in order to obtain a court order requiring FDA to comply within a reasonable time period.

The states have expressed concerns about the lack of FDA action on similar petitions submitted under section 403A following enactment of that provision as part of the Nutrition Labeling and Education Act of 1990. Accordingly, the provisions in this legislation are also made applicable to the petitions under section 403A(b).

Imminent hazard authority. This paragraph provides that a state may take an emergency action in those situations where it is needed to address an imminent hazard to health that is likely to result in serious adverse health consequences or death. This standard for emergency action is used elsewhere for comparable matters in the

Federal Food, Drug, and Cosmetic Act. When this occurs, the state must notify FDA about the matter to determine that FDA has not initiated enforcement action and must submit a petition within 30 days for an exemption from national uniformity or to establish a national standard. The state is required to institute enforcement action with respect to the matter within 30 days after it establishes the nonuniform emergency requirement.

Action on petition. This paragraph provides for action on the petition under the imminent hazard authority. For a petition submitted under the imminent hazard provision, FDA must take final agency action not later than 7 days after it was received. The failure of FDA to comply with this deadline constitutes final agency action in order to obtain judicial review and a court order regarding FDA compliance.

Duration. This paragraph provides that the imminent hazard requirement remains in effect until FDA takes final agency action on the petition.

No effect on product liability law. This subsection states that the legislation has no effect on the existing tort law that governs product liability in any state.

No effect on identical law. If a state statute imposes the same requirement as the federal law, a state or local government may enforce that state statute in the state courts. This is true even if FDA has taken no action either to bring enforcement proceedings in the courts or to publish a proposed regulation or to adopt an informal guidance. Accordingly, states remain free to enforce state provisions that are identical to federal law unless and until FDA acts to establish a national standard. Where FDA has particularized a statutory requirement through regulations, the state must then enforce the identical requirements that are imposed by federal regulations. This provision therefore recognizes the legitimate need of state enforcement authorities to take enforcement action where FDA does not act, as long as the action is taken under identical statutory provisions.

No effect on certain state law. There are a number of state and local laws that constitute traditional local food enforcement activities. Paragraph (1) provides for specific exclusions of state laws. The bill excludes from the requirements of this legislation state and local laws regarding freshness dating, open date labeling, grade labeling, state inspection stamps, religious dietary labeling, organic or natural designations, return bottle labeling, unit pricing, and statements of geographic origin. Paragraph (2) provides for exclusions for certain actions under the FDA Food Code. This section exempts any consumer advisory relating to food sanitation that is imposed on a food establishment or is recommended by the Secretary under the FDA Food Code. This reference includes shellfish warnings that are required by several states and that would remain in effect under this exemption.

Definition. This subsection provides a definition of the term "requirement." Throughout both section 403A and section 403B, the term "requirement" is used to refer to both mandatory action and to any prohibition established under the Federal Food, Drug, and Cosmetic Act or the Fair Packaging and Labeling Act or by any regulation issued thereunder, or by a court order relating to those

two statutes. The term "requirement" does not extend to informal enforcement procedures such as action levels or guidance.

Subsection 2(c). Conforming amendment. The requirements for FDA action on petitions for an exemption or a national standard under section 403B(c) (3) and (4), are made applicable to the petition for an exemption established under section 403A(b) as it was added by the Nutrition Labeling and Education Act. This will bring all exemption and uniformity petitions into conformity.

III. Legislative History and Committee Vote

COMMITTEE VOTE

In compliance with paragraph 7 of rule XXVI of the Standing Rules of the Senate, the following statement is made concerning the votes of the Committee in its consideration of the bill:

The Committee met in open session on June 29, 2000 and, in the presence of a quorum, approved an amendment in the nature of a substitute. The Committee then ordered that the bill be favorably reported by a voice vote.

IV. Regulatory Impact Statement

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the following evaluation is made concerning the regulatory impact of enacting this legislation:

This bill establishes national uniformity for food safety warnings. Under current law, food manufacturers and distributors must comply with whatever food safety warning requirements are imposed by individual states and localities as well as the federal government. Nationally uniform food safety warning requirements should pose less burden on the regulated industries. No increase in paperwork or recordkeeping requirements is anticipated for those who must comply with uniform national food safety warning requirements. There should not be an adverse impact on the personal privacy of individuals affected by this legislation.

V. Budgetary Impact of the Bill

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the following letter has been received from the Congressional Budget Office regarding the budgetary impact of the bill:

U.S. Congress,
Congressional Budget Office,
Washington, DC, July 25, 2000.

Hon. Richard G. Lugar,
Chairman, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1155, the National Uniformity for Food Act of 2000.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Christopher J. Topoleski.

Sincerely,

STEVEN LIEBERMAN
(For Dan L. Crippen, Director).

Enclosure.

S. 1155—National Uniformity for Food Act of 2000

Summary: The National Uniformity for Food Act of 2000 would amend the Federal Food, Drug, and Cosmetic Act (FDCA) to prohibit states or local governments from establishing or continuing in effect requirements that are not identical to specified FDCA provisions for:

- Labeling special dietary foods and dietary supplements;
- Defining food adulteration, excluding aspects of food sanitation that will remain primarily a state responsibility; and
- Issuing food warning notification concerning the safety of food and its constituents.

S. 1155 would establish a petition process by which state, local, and national food safety and warning notification requirements would be set, and would allow for a state or local government to establish a requirement that would be in conflict with national uniformity standards if the state requirement is needed to prevent imminent hazard to public health. Assuming appropriation of the necessary amounts, CBO estimates that implementing S. 1155 would cost $9 million in 2001 and $81 million over the 2001–2005 period. Those costs would be incurred by the Food and Drug Administration (FDA).

The bill would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

The National Uniformity for Food Act of 2000 would preempt certain state laws governing food safety and the issuance of warning notifications. Those preemptions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The costs of complying with those mandates, however, would be minimal and would not exceed the threshold established in UMRA ($55 million in 2000, adjusted annually for inflation). If states chose to seek exemptions from the federal prohibition, they may incur costs dependent the type of requirement involved and subsequent legal actions. Any such costs, however, would be incurred voluntarily and thus would not be associated with the mandate. The bill contains no new private-sector mandates as defined in UMRA.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 1155 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2000	2001	2002	2003	2004	2005
SPENDING SUBJECT TO APPROPRIATION						
FDA Spending Under Current Law:						
Estimated Authorization Level [1]	1,049	1,090	1,125	1,161	1,197	1,234
Estimated Outlays	1,038	1,110	1,112	1,142	1,176	1,213
Proposed Changes:						
Estimated Authorization Level	0	10	12	21	24	15
Estimated Outlays	0	9	12	20	24	16

	By fiscal year, in millions of dollars—					
	2000	2001	2002	2003	2004	2005
FDA Spending Under S. 1155:						
Estimated Authorization Level [1]	1,049	1,100	1,137	1,182	1,221	1,249
Estimated Outlays	1,038	1,119	1,124	1,162	1,200	1,229

[1] The 2000 level is the amount appropriated for that year. The 2001–2005 levels are baseline projections that reflects annual increases for anticipated inflation.

Basis of estimate: For this estimate, CBO assumes that S. 1155 will be enacted near the start of fiscal year 2001 and that appropriations will be provided to pay for the additional resources needed by FDA to fulfill the requirements of this legislation. CBO also assumes that such appropriations will be provided by the start of each fiscal year and that outlays will follow the historical spending patterns of FDA.

The National Uniformity for Food Act of 2000 would amend the Federal Food, Drug, and Cosmetic Act to prohibit states or local governments form establishing or continuing in effect requirements for:

- Labeling special dietary foods and dietary supplements that is not identical to specified FDCA provisions, designed to provide the same type of national uniformity for special dietary food and supplement labeling as now applies to other food labeling;
- Defining food adulteration that is not identical to specified FDCA provisions, excluding aspects of food sanitation which will remain primarily a state responsibility; and
- Issuing warning notifications concerning the food's safety that are not identical to FDCA provisions. State level food warnings may not be issued unless the federal government requires that the warnings be issued for specific foods.

The bill would establish a petition process by which notification requirements for state, local, and national food safety and warnings would be established. Under the petition process, states could solicit an exemption of state or local notification requirements from national uniformity standards. Currently, specific state and local requirements exist that may not be nationally applicable. In addition, state petitions could also request a national uniformity decision.

Further, S. 1155 would allow a state to establish a requirement that would otherwise violate proposed FDCA uniformity standards if the requirement is needed to address an imminent adverse health consequence.

Finally, the bill specifically would exempt the following activities from national uniformity: freshness dating, open date labeling, state inspection stamps, units pricing, religious dietary labeling, organic or natural designation, returnable bottle labeling, statement of geographical origin, and consumer advisories regarding food sanitation for food service establishments.

Based on information from the FDA and a review of states likely to be affected by the bill, CBO estimates that states would submit about 80 petitions during 2001. CBO estimates that FDA would spend an average of about $1 million per petition. As a result, we estimate that implementing S. 1155 would cost $81 million over the 2001–2005 period. The majority of the costs of this bill would result from reviewing and issuing final determinations on petitions

filed for existing and future food safety and warning notification laws. The remainder of the costs would stem from promulgating regulations to implement the bill.

The bill would impose restrictive limits on the time that FDA would have to review petitions and take final action. CBO assumes FDA would not be able to fully comply with the time limits imposed under the bill. CBO's estimate of the annual cost of the petition review process allows for such a delay. The estimate does not include any legal costs to the federal government that may be incurred should states, local governments, or private entities seek to challenge FDA's final rulings on petitions.

Pay-as-you-go considerations: None.

Estimated impact on state, local, and tribal governments: S. 1155 would prohibit states from establishing food safety requirements different from federal guidelines. The bill also would prohibit states from requiring any warning notifications concerning food safety that are not identical to federal requirements. These preemptions of state regulatory authority would be intergovernmental mandates as defined in UMRA. However, the costs of complying with those mandates would be minimal and would not exceed the threshold established in UMRA ($55 million in 2000, adjusted annually for inflation).

Existing state laws that are not identical to federal food safety and warning notification requirements addressed by the bill could remain in effect for 180 days after enactment. During those 180 days, a state may petition the FDA for an exemption to the preemption or for the establishment of a national standard, and until the FDA takes final administrative action on the petition, the existing state law would remain in effect. States may also impose requirements that would not be identical to federal requirements in order to address an imminent health hazard. After issuing such requirements, states would have to file a petition with the FDA within 30 days. If states chose to petition FDA for exemptions from the federal prohibition on differing food safety requirements and warning notifications, they may incur costs depending on the type of requirement involved and subsequent legal actions. Any such costs, however, would be incurred voluntarily and thus would not be associated with the mandate.

Estimated impact on the private sector: S. 1155 contains no new private-sector mandates as defined in UMRA.

Estimate prepared by: Federal Costs: Julia Christensen and Christopher J. Topoleski. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Jean Wooster.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made in the bill, as reported are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new material is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. * * *

* * * * * * *

SEC. 403A. * * *

(a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

* * * * * * *

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A), **[**or**]**

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under section 403(r)(5)(B). Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990**[**.**]**,

(6) any requirement for the labeling of food described in section 403(j), or 403(s), that is not identical to the requirement of such section, or

(7) any requirement for a food described in section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7), 402(c), 402(f), 402(g), 404, 406, 408, 409, 512, or 721(a), that is not identical to the requirement of such section.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a). *The requirements of paragraphs (3) and (4) of section 403B(b) shall apply to any such petition, in the same manner and to the same extent as the requirements apply to a petition described in section 403B(b).*

* * * * * * *

SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTIFICATION REQUIREMENTS.

(a) UNIFORMITY REQUIREMENT.—

(1) IN GENERAL.—Except as provided in subsections (b) and (c), no State or political subdivision of a State may, directly or indirectly, establish or continue in effect under any authority any notification requirement for a food that provides for a warning concerning the safety of the food, or any component or

package of the food, unless such a notification requirement has been prescribed under the authority of this Act and the State or political subdivision notification requirement is identical to the notification requirement prescribed under the authority of this Act.

(2) DEFINITIONS.—For purposes of paragraph (1)—

(A) the term "notification requirement" includes any mandatory disclosure requirement relating to the dissemination of information about a food by a manufacturer or distributor of a food in any manner, such as through a label, labeling, poster, public notice, advertising, or any other means of communication, but not relating to notification, disclosure, or other dissemination of information by a State or political subdivision;

(B) the term "warning", used with respect to a food, means any statement, vignette, or other representation that indicates, directly or by implication, that the food presents or may present a hazard to health or safety; and

(C) a reference to a notification requirement that provides for a warning shall not be construed to refer to any requirement or prohibition relating to food safety that does not involve a notification requirement.

(b) EXEMPTIONS AND NATIONAL STANDARDS.—

(1) EXEMPTIONS.—Any State may petition the Secretary to provide by regulation, after providing notice and an opportunity for written and oral presentation of views during a public comment period described in paragraph (3), an exemption from paragraph (6) or (7) of section 403A(a) or subsection (a), for a requirement of the State or a political subdivision of the State. The Secretary may provide such an exemption, under such conditions as the Secretary may impose, for such a requirement that—

(A) protects an important public interest that would otherwise be unprotected, in the absence of the exemption;

(B) would not cause any food to be in violation of any applicable requirement or prohibition under Federal law; and

(C) would not unduly burden interstate commerce, balancing the importance of the public interest of the State or political subdivision against the impact on interstate commerce.

(2) NATIONAL STANDARDS.—Any State may petition the Secretary to establish by regulation, after providing notice and an opportunity for written and oral presentation of views during a public comment period described in paragraph (3), a national standard respecting any requirement under this Act or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) relating to the regulation of a food.

(3) ACTION ON PETITIONS.—

(A) PUBLICATION.—Not later than 30 days after receipt of any petition under paragraph (1) or (2), the Secretary shall publish such petition in the Federal Register for public comment during a period specified by the Secretary.

(B) TIME PERIODS FOR ACTION.—Not later than 60 days after the end of the period for public comment, the Secretary shall take action on the petition. If the Secretary is

unable to take action on the petition during the 60-day period, the Secretary shall inform the petitioner, in writing, the reasons that taking the action is not possible, the date by which the action will be taken, and the action that will be taken or is likely to be taken. In every case, the Secretary shall take action on the petition not later than 120 days after the end of the period for public comment.

(4) JUDICIAL REVIEW.—The failure of the Secretary to comply with any requirement of this subsection shall constitute final agency action for purposes of judicial review. If the court conducting the review determines that the Secretary has failed to comply with the requirement, the court shall order the Secretary to comply within a period determined to be appropriate by the court.

(c) IMMINENT HAZARD AUTHORITY.—

(1) IN GENERAL.—A State may establish a requirement that would otherwise violate paragraph (6) or (7) of section 403A(a) or subsection (a), if—

(A) the requirement is needed to address an imminent hazard to health that is likely to result in serious adverse health consequences or death;

(B) the State has informed the Secretary about the matter involved and the Secretary has not initiated enforcement or other regulatory action with respect to the matter;

(C) a petition is submitted by the State under subsection (b) for an exemption or national standard relating to the requirement not later than the date that the State establishes the requirement under this subsection; and

(D) the State institutes enforcement action with respect to the matter in compliance with State law following submission of such petition.

(2) ACTION ON PETITION.—

(A) IN GENERAL.—The Secretary shall take action on any petition submitted under paragraph (1)(C) not later than 7 days after the petition is received, notwithstanding subsection (b)(3)(B) and the public comment requirements of subsection (b).

(B) JUDICIAL REVIEW.—The failure of the Secretary to comply with the requirement described in subparagraph (A) shall constitute final agency action for purposes of judicial review. If the court conducting the review determines that the Secretary has failed to comply with the requirement, the court shall order the Secretary to comply within a period determined to be appropriate by the court.

(3) DURATION.—If a State establishes a requirement in accordance with paragraph (1), the requirement may remain in effect until the Secretary acts on a petition submitted under paragraph (1)(C).

(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect the product liability law of any State.

(e) NO EFFECT ON IDENTICAL LAW.—Nothing in this section or section 403A relating to a food shall be construed to prevent a State or political subdivision of a State from establishing, enforcing, or continuing in effect a requirement that is identical to a requirement

of this Act, whether or not the Secretary has promulgated a regulation or issued a policy statement relating to the requirement.

(f) NO EFFECT ON CERTAIN STATE LAW.—Nothing in this section or section 403A relating to a food shall be construed to prevent a State or political subdivision of a State from establishing, enforcing, or continuing in effect a requirement relating to—

(1) freshness dating, open date labeling, grade labeling, a State inspection stamp, religious dietary labeling, organic or natural designation, returnable bottle labeling, unit pricing, or a statement of geographic origin; or

(2) a consumer advisory relating to food sanitation that is imposed on a food service establishment, or that is recommended by the Secretary, under part 3–6 of the Food Code issued by the Food and Drug Administration and referred to in the notice published at 64 Fed. Reg. 8576 (1999) (or any corresponding similar provision of such a Code).

SEC. [403B] *403C.* DIETARY SUPPLEMENT LABELING EXEMPTIONS.

(a) IN GENERAL.—A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

* * * * * * *

SEC. [403C] *403D.* DISCLOSURE.

(a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(I)(2).

* * * * * * *

○